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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,152	08/24/2001	Hisashi Narimatsu	2139.25	1765
5514	7590	11/04/2005	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			RAO, MANJUNATH N	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,152

Applicant(s)

NARIMATSU ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5-25,29-31,33,38,48,49,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,5-7,17,25,29-31,33,48,49 and 53 is/are allowed.
- 6) ☒ Claim(s) 8,9,13-16,18-24,38 and 54 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 5-25, 29-31, 33, 38, 48, 49, 53, 54 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 4-20-05 in response to the Office action dated 3-15-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The previous indication of allowance has been withdrawn as some new issues have been identified. Any inconvenience caused is deeply regretted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 8, 13 are directed to a transformant harboring the DNA with SEQ ID NO:2 and a process of using such transformant for making the polypeptide. Since the claims are drawn to non-specific "transformant", said term "transformant" could include humans and any claim drawn to humans is considered as non-statutory. Therefore claims 8, 13 are rejected as it is directed to a non-statutory subject matter. Examiner suggests deletion of the claim.

Claims 18-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 18-19 recite the phrase "enzyme source". Since

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applicants do not specify or distinguish between the different enzyme source and since the claim recites the entire source to be part of the reaction, the above phrase could read on humans as “enzyme source” and any claim drawn to humans is considered non-statutory. Therefore claims 8, 13 are rejected as it is directed to a non-statutory subject matter. Examiner suggests deletion of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18-19 recite the phrase “enzyme source”. The metes and bounds of this phrase is not clear to the Examiner. It is not clear whether microorganisms, animal cells or plants cells or even the entire animals or plants are contemplated as “enzyme source”. Examiner requests clarification or an amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 13-16, 20-24, 38, 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making a transformant wherein the host is a microorganism, an animal cell, a plant cell or an insect cell and wherein the polynucleotide with

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SEQ ID NO:2 is used in said transformation, does not reasonably provide enablement for transforming a non-human animal or a transgenic plant and use of such transformed animal or plant in any of the claimed methods for making or using the polypeptide encoded by the transformed polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 9, 13-16, 20-24, 38, 54 are so broad as to encompass transformation of any non-human animal or any transgenic plant using the polynucleotide with SEQ ID NO:2 for making the encoded polypeptide by way of collecting the milk or tissue of the transformed animal or plant parts and isolating the expressed polypeptide. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of animals and plants transformed broadly encompassed by the claims. It is well known in the art that making transgenic animals and plants is a special area by itself and encompasses a large number of variable factors for the successful transformation. There is no universal method in the art which can be used to transform any animal or any plant using any polynucleotide. Therefore, in order to transform any or all plants and animals, using the polynucleotide with SEQ ID NO:1,

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requires a knowledge of and guidance with regard to which specific animal or plant host is required, whether such plant or animal is tolerant to modification and detailed knowledge of the ways in which each of said animal and plant can be transformed. However, in this case the disclosure is totally silent on transformation of animals and plants using the polynucleotide SEQ ID NO: 1 and is limited to the methods of transforming microorganisms or individual animal cells. It would require undue experimentation of the skilled artisan to transform any or all plant/animals to make and use the claimed polypeptides. The specification is limited to teaching the use of SEQ ID NO: 1 to transform microorganisms but provides no guidance with regard to transformation of animals and plants and methods of using such transformed animals and plants for production of encoded polypeptide. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting which animal or plant can be successfully transformed with SEQ ID NO: 1, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis and transformation of microorganisms are known, and it is routine in the art to transform microorganisms, the same is not true for transformation of animals and plants and any such method with a reasonable expectation of success in obtaining the desired activity/utility of the transformed animal or plant are limited and the result of such transformation is unpredictable. In addition, one skilled in the art would expect any tolerance to such modification for a given animal or plant to diminish with each further and additional modification.

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The specification does not support the broad scope of the claims which encompass transformation of any or all animals and plants because the specification does not establish: (A) a single method that can be used to transform any plant or animal; (B) the general tolerance of said animals and plants to transformation and extent of such tolerance; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all animals as transformants that can be made using SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of animals and plants having the desired characteristics for transformation is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Conclusion

Claims 2, 5-7, 17, 25, 29-31, 33 48, 49, 53, are allowable. Claims 10-12 are objected as depending on rejected claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura

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Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao, Ph.D.
Primary Examiner
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October 26, 2005